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A pragmatic randomised controlled trial of hydrotherapy and land exercises on global well-being in patients with rheumatoid arthritis (RA).

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
14/07/2009

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265126507

Study information

Scientific Title

Study objectives
Hydrotherapy (exercise in heated water) is superior to exercise on land in terms of overall well-being, physical function and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Rheumatoid arthritis (RA)

Interventions
Men and women aged 18 years or older with RA (meeting American College of Rheumatology criteria) attending the Rheumatology out-patient department will be invited to participate. Many patients with RA may have previously received physiotherapy or hydrotherapy treatment. To reduce carry over effects, those having either physiotherapy or hydrotherapy, for any reason, in the previous 6 months will be excluded.

Patients attending the Rheumatology out-patient department with rheumatoid arthritis will be provided with a patient information leaflet (providing information about the study) and invited to complete a short screening questionnaire. Patients will be asked to express their interest in participating in the study at the end of the screening questionnaire. Patients will be asked to return this completed form to the Selly Oak Hospital Physiotherapy Department in the stamped addressed envelope provided.

Patients interested in participating will then be asked to attend for physiotherapy assessment. The physiotherapist will carry out a full physical assessment and apply inclusion and exclusion criteria. Patients not interested in the study, or who do not meet criteria, will he offered physiotherapy in the usual way as judged appropriate by the assessing physiotherapist. Those who are uncertain will be given an opportunity to discuss the study and will then be included if they meet the criteria and wish to be involved.

Suitable patients will be asked for informed consent in writing and given a signed copy for their records.

Staff in the department of physiotherapy will make all initial assessments. However treatments in the study will be managed by one of two senior physiotherapists. These staff will make equal contributions to land exercises and hydrotherapy.

Interventions

The interventions have been designed to compare the effects of water immersion with exercise with land exercise. In all cases, patients will be treated once a week for 6 successive weeks. Each session will last approximately 30 minutes. Patients will be given written instructions on appropriate home exercises on completion of the intervention. Advice will be individualised as necessary according to current best practice.

Patients will be randomised to one of two interventions in equal proportions, as follows:

A. Hydrotherapy:
Groups of 3 or 4 patients will, attend for hydrotherapy. Each session will consist of initial warm-up (approximately 5 minutes; including stretching and immobilisation). Muscle strengthening and joint mobility exercises will follow. Specific exercises will be tailored according to individual needs but will incorporate buoyancy assisted and resisted exercises for upper and lower limbs. Exercises will be progressed as required and related to functional activities where possible. A cool down phase (including gentle mobilisation and stretching) will conclude the session.

B. Land exercise:
Groups of six patients will receive instruction on appropriate exercise on land. Sessions will consist of an initial warm up (approximately 5 minutes; including stretching and mobilisation). Muscle strengthening and joint mobility exercises will follow. Specific exercises will be tailored according to individual needs with a focus on functional aspects such as sit to stand exercises and reaching above head height. Exercises will be progressed as required. A cool down phase will conclude each session.

One of two experienced senior physiotherapists will supervise all treatment groups. This reduces the risk of biases associated with a particular therapist. Exercise sessions will be at the same time of day each week.

Our hydrotherapy pool permits a maximum of only four patients to be treated safely at any one time. The choice of number therefore reflects safe and effective use of resources. Six patients will be treated in each land exercise group. We believe that group sizes are sufficiently similar to allow valid comparisons between treatment groups.

Withdrawal - Other interventions

At all times patient safety will be paramount and patients may be withdrawn at any time by the treating physiotherapist or a physician involved in the patients care, as determined by their professional judgement. Patients will also have the option of withdrawing from the study at any time without the necessity for giving a reason.

Since this is a pragmatic trial no restrictions will be placed on use of other modalities by patients except for surgery. Changes in concomitant therapies such as steroids, disease-modifying antirheumatic drugs (DMARDs) or non-steroidal anti-inflammatory drugs (NSAIDs) will be permitted to reflect routine practice. A detailed inventory of all therapies will be kept at the outset and at study end. Changes across groups will be compared and, if appropriate, statistical adjustments made when comparing the effect of our interventions.

Randomisation and Conduct

Patients will be randomised to groups A or B using sealed envelopes indicating treatment allocation. Envelopes will be prepared before the study begins and ordered as determined by flipping a virtual coin and heads designated hydrotherapy, tails land exercise. Randomisation and treatment allocation will be done by a research assistant not involved in the conduct of the study and at a distance from the treatment area.

Treatment groups will be convened when sufficient numbers have accrued to assemble at least one whole group. Patients will be permitted to book into pre-arranged treatment slots according to their allocation. Flexibility in booking times will he allowed to encourage participation.

Patients will be asked to attend weekly. Missed appointments for any reason will be recorded and compared across groups. Those defaulting on 2 or more of their 6 visits will be regarded as non-responders for the primary outcome. Patients will also be encouraged to maintain loyalty with their patient partners and treating physiotherapist to control for group and therapist effects.

NB: All assessments and treatments are within the scope of normal clinical practice.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
A research assistant blind to treatment allocation will collect initial and final outcome measurements.
Primary Outcome measure: the proposed primary outcome measures change in self-rated global impression, a validated measure of treatment effect. This measure has previously been used in clinical trials of exercise in fibromyalgia and chronic fatigue syndrome. Effect of treatment is measured as change on a 7-point scale ranging from 1 (very much worse) to 7 (very much better). Participants scoring 6 or 7 will be regarded as responders and others as non-responders.

Secondary outcome measures
Secondary outcome measures will include:
- Pain measured on a 10 cm visual analogue scale

- Physical function based on the health assessment questionnaire (HAQ score), 10 metre walk speed and quality of life measured by the first part of the Euroqol EQ-SD questionnaire that records problems in five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression).

Tertiary outcomes:
We propose to compare cost-effectiveness of hydrotherapy and land exercises by using data from secondary outcome measures collected, particularly utility scores calculated from EQ-SD and nationally available sources on the cost of health services.

Overall study start date
15/10/2003

Completion date
15/10/2008

Eligibility

Key inclusion criteria
a. Invitation - potential volunteers will be invited to participate when they attend their Rheumatology out-patient appointment sessions. They will be provided with a "Patient Information Leaflet" and a short screening Questionnaire with a section to state their interest in participation

b. Consent - Informed consent for participation in the study will be sought from all volunteers and consent forms will be completed. A copy of this form will be retained by each patient.

c. Patient Selection: Inclusion criteria:

1. Ability to understand the purpose of the study, give informed consent in writing and follow simple instructions
2. Age >18 years
3. Stable disease modifying drugs for 6 weeks before study entry
4. No injected steroids 4 weeks prior to study entry
5. Stable non-steroidal anti-inflammatory drugs for 2 weeks before entry
6. No surgery 3 months preceding study or planned surgery within 3 months of entry
7. Functional class I, II, III

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria
1. Patients who have received physiotherapy or hydrotherapy in the past 6 months
2. Any medical condition that in the opinion of the investigators would cause the study to be detrimental to the patient
3. Known chlorine sensitivity
4. Open or infected skin wound
5. Poorly controlled epilepsy
6. Incontinence of faeces
7. Weight >16 stones (102 kg) - inability to meet emergency procedures in our hydrotherapy pool
8. Pregnancy or breast-feeding
9. Fear of water precluding hydrotherapy
10. Inability to communicate with therapist effectively
11. Unlikely to comply with therapy in the opinion of a physician
12. Known carriage of methicillin- resistant Staphylococcus aureus (upper respiratory tract)

Date of first enrolment
15/10/2003

Date of final enrolment
15/10/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Rheumatology
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall

London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2007		Yes	No